

considered by Examiner
12/28/09
/Kevin K. Hill/



S/N 10/815,262

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: John F. Engelhardt et al.

Examiner: Kevin Hill

Serial No.: 10/815,262

Group Art Unit: 1633

Filed: March 31, 2004

Docket No.: 875.074US1

Customer No.: 21186

Confirmation No.: 7471

Title: COMPOUNDS AND METHODS TO ENHANCE rAAV TRANSDUCTION

SUPPLEMENTAL RULE 132 DECLARATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We, Dr. John Engelhardt and Dr. Ziyi Yan, declare and say as follows:

1. We are two of the named co-inventors of the above-identified application and we make this Declaration in support of the patentability of the pending claims.

2. In the Office Action mailed August 6, 2009 for the above-referenced matter, the Examiner asserted that the practice of the claimed methods would require undue experimentation because, among other things, the specification does not teach *in vivo* dosing and dosage regimens to avoid toxicity.

3. As discussed in the Amendment which accompanies this Supplemental Declaration, it is well within the skill of the art worker to select nontoxic doses of one or more compounds and suitable routes of administration for those compounds. In particular, with regard to nontoxic doses and suitable routes of administration for certain compounds useful to enhance recombinant adeno-associated virus (rAAV) transduction, the Examiner is requested to consider the following.

4. A toxicity study conducted by one of skill in the art might include administering to a non-human mammal one or more doses of a selected compound by a particular route. Then, at one or more times after that administration, tissue samples from those non-human mammals and controls would be harvested and analyzed.